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EXAMINER
UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,270	MACK ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-55 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claim 1 links inventions 1-16. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1 and 2 are drawn to an assay for the detection of an increased possibility of melanoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of melanoma, classified in Class 435, subclass 4, 6.

Group 2. Claims 1 and 3 are drawn to an assay for the detection of an increased possibility of glioblastoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of glioblastoma, classified in Class 435, subclass 4, 6.

Group 3. Claims 1 and 4 are drawn to an assay for the detection of an increased possibility of colonic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of colonic adenocarcinoma, classified in Class 435, subclass 4, 6.

Group 4. Claims 1 and 5 are drawn to an assay for the detection of an increased possibility of prostatic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of prostatic adenocarcinoma, classified in Class 435, subclass 4, 6.

Group 5. Claims 1 and 6 are drawn to an assay for the detection of an increased possibility of ovarian adenocarcinoma in a human

patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of ovarian adenocarcinoma, classified in Class 435, subclass 4, 6.

Group 6. Claims 1 and 7 are drawn to an assay for the detection of an increased possibility of breast cancer in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of breast cancer, classified in Class 435, subclass 4, 6.

Group 7. Claims 1 and 8 are drawn to an assay for the detection of an increased possibility of pancreatic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of pancreatic adenocarcinoma, classified in Class 435, subclass 4, 6.

Group 8. Claims 1 and 9 are drawn to an assay for the detection of an increased possibility of lung adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining

whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of lung adenocarcinoma, classified in Class 435, subclass 4, 6.

Group 9. Claims 1 and 2 are drawn to an assay for the detection of an increased possibility of melanoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of melanoma, classified in Class 435, subclass 4, 7.1.

Group 10. Claims 1 and 3 are drawn to an assay for the detection of an increased possibility of glioblastoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of glioblastoma, classified in Class 435, subclass 4, 7.1.

Group 11. Claims 1 and 4 are drawn to an assay for the detection of an increased possibility of colonic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether

the patient has an increased possibility of colonic adenocarcinoma, classified in Class 435, subclass 4, 7.1.

Group 12. Claims 1 and 5 are drawn to an assay for the detection of an increased possibility of prostatic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of prostatic adenocarcinoma, classified in Class 435, subclass 4, 7.1.

Group 13. Claims 1 and 6 are drawn to an assay for the detection of an increased possibility of ovarian adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of ovarian adenocarcinoma, classified in Class 435, subclass 4, 7.1.

Group 14. Claims 1 and 7 are drawn to an assay for the detection of an increased possibility of breast cancer in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of breast cancer, classified in Class 435, subclass 4, 7.1.

Group 15. Claims 1 and 8 are drawn to an assay for the detection of an increased possibility of pancreatic adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of pancreatic adenocarcinoma, classified in Class 435, subclass 4, 7.1.

Group 16. Claims 1 and 9 are drawn to an assay for the detection of an increased possibility of lung adenocarcinoma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of lung adenocarcinoma, classified in Class 435, subclass 4, 7.1.

Group 17. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in reactive myointimal cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 7.1.

Group 18. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising

providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in reactive macrophages cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 7.1.

Group 19. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in reactive myointimal cells and macrophages cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 7.1.

Group 20. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in reactive myointimal cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 6.

Group 21. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an

increased presence of GPR19 in reactive macrophages cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 6.

Group 22. Claim 10 is drawn to an assay for the detection of an increased possibility of atherosclerosis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in reactive myointimal cells and macrophages relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of atherosclerosis, classified in Class 435, subclass 4, 6.

Group 23. Claim 11 is drawn to an assay for the detection of an increased possibility of Crohn's disease in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Crohn's disease , classified in Class 435, subclass 4, 7.1.

Group 24. Claim 11 is drawn to an assay for the detection of an increased possibility of Crohn's disease in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom

determining whether the patient has an increased possibility of Crohn's disease , classified in Class 435, subclass 4, 6.

Group 25-48. Claim 12 is drawn to an assay for the detection of an increased possibility of Asthma in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in at least one of alveolar macrophages, hyperplastic respiratory epithelium, squamous metaplastic epithelium and inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Asthma , classified in Class 435, subclass 4, 7.1. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 24 by factorial analysis, thus 4(n!) = 24. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 49-72. Claim 12 is drawn to an assay for the detection of an increased possibility of Asthma in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in at least one of alveolar macrophages, hyperplastic respiratory epithelium, squamous metaplastic epithelium and inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Asthma , classified in Class

435, subclass 4, 6. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 24 by factorial analysis, thus 4(n!) = 24. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 73. Claim 13 is drawn to an assay for the detection of an increased possibility of ulcerative colitis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of ulcerative colitis, classified in Class 435, subclass 4, 6.

Group 74. Claim 13 is drawn to an assay for the detection of an increased possibility of ulcerative colitis in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of ulcerative colitis, classified in Class 435, subclass 4, 7.1.

Group 75-80. Claim 14 is drawn to an assay for the detection of an increased possibility of Bronchitis in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as

disclosed in the specification, and determining whether there is an increased presence of GPR19 in at least one of alveolar macrophages, hyperplastic respiratory epithelium, squamous metaplastic epithelium relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Bronchitis , classified in Class 435, subclass 4, 7.1. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 81-86. Claim 14 is drawn to an assay for the detection of an increased possibility of Bronchitis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in at least one of alveolar macrophages, hyperplastic respiratory epithelium, squamous metaplastic epithelium relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Bronchitis , classified in Class 435, subclass 4, 6. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but

rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 87-92. Claim 15 is drawn to an assay for the detection of an increased possibility of Allergic rhinitis in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in at least one of inflammatory cells, hyperplastic respiratory epithelium, squamous metaplastic epithelium relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Allergic rhinitis , classified in Class 435, subclass 4, 7.1. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 93-98. Claim 15 is drawn to an assay for the detection of an increased possibility of Allergic rhinitis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in at least one of inflammatory cells, hyperplastic respiratory epithelium, squamous metaplastic epithelium relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Allergic rhinitis , classified

in Class 435, subclass 4, 6. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 99. Claim 16 is drawn to an assay for the detection of an increased possibility of Pneumonia in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in alveolar macrophages relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Pneumonia , classified in Class 435, subclass 4, 7.1

Group 100. Claim 16 is drawn to an assay for the detection of an increased possibility of Pneumonia in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in alveolar macrophages relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Pneumonia , classified in Class 435, subclass 4, 6.

Group 101. Claim 17 is drawn to an assay for the detection of an increased possibility of Rheumatoid arthritis in a human patient comprising providing a binding partner specific for GPR 19

polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Rheumatoid arthritis , classified in Class 435, subclass 4, 7.1

Group 102. Claim 17 is drawn to an assay for the detection of an increased possibility of Rheumatoid arthritis in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in inflammatory cells relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Rheumatoid arthritis , classified in Class 435, subclass 4, 6.

Group 103. Claim 18 is drawn to an assay for the detection of an increased possibility of Congestive heart failure in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in myocytes relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Congestive heart failure , classified in Class 435, subclass 4, 7.1

Group 104. Claim 18 is drawn to an assay for the detection of an increased possibility of Congestive heart failure in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining

whether there is an increased presence of GPR19 increased presence of GPR19 in myocytes relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Congestive heart failure , classified in Class 435, subclass 4, 6.

Group 105-107. Claim 19 is drawn to an assay for the detection of an increased possibility of Parkinson's disease in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in at least one of neurons and macrophages relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Parkinson's disease , classified in Class 435, subclass 4, 7.1. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 3. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 108-110. Claim 19 is drawn to an assay for the detection of an increased possibility of Parkinson's disease in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence of GPR19 in at least one of neurons and macrophages relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Parkinson's disease ,

classified in Class 435, subclass 4, 6. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 3. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 111-116. Claim 20 is drawn to an assay for the detection of an increased possibility of Altzheimer's disease in a human patient comprising providing a binding partner specific for GPR 19 polypeptide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 in at least one of macrophages, tangles and neuritic plaques relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Altzheimer's disease , classified in Class 435, subclass 4, 7.1. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 117-122. Claim 20 is drawn to an assay for the detection of an increased possibility of Altzheimer's disease in a human patient comprising providing a binding partner specific for GPR 19 polynucleotide, as disclosed in the specification, and determining whether there is an increased presence of GPR19 increased presence

of GPR19 in at least one macrophages, tangles and neuritic plaques relative to corresponding unaffected tissue and therefrom determining whether the patient has an increased possibility of Altzheimer's disease , classified in Class 435, subclass 4, 6. It is noted that the number of combinations of cell types to be assayed, and therefore the number of groups has been determined to be 6 by factorial analysis, thus 3(n!) = 6. It is noted for Applicant's information that this is **not** an election of species requirement, but rather a requirement to elect a specific group for examination consisting of a single combination of cell types to be assayed.

Group 123. Claims 21-22 are drawn to kit comprising an antibody for GPR 19 classified in Class 530, subclass 387.1.

Group 124. Claims 21-22 are drawn to kit comprising a polynucleotide probe for GPR 19, as disclosed in the specification, classified in Class 536, subclass 23.1.

Group 125. Claims 23-24, 29-30, 35, 38, 39, 44, 45, 50, 53 are drawn to composition comprising GPR 19 protein as disclosed in the specification classified in Class 530, subclass 350+.

Group 126. Claims 23-24, 29-30, 35, 38, 39, 44, 45, 50, 53 are drawn to composition comprising GPR 19 polynucleotide as disclosed in the specification classified in Class 536, subclass 23.1.

Group 127. Claims 25, 26, 31, 32, 36, 40, 41, 46, 47, 51, 54 are drawn to a method of manufacturing a medicament comprising a GPR 19 agonist classified in Class 530, subclass 300+.

Group 128. Claims 27, 28, 33, 34, 37, 42, 43, 48, 49, 52, 55 are drawn to a method of manufacturing a medicament comprising a GPR 19 antagonist classified in Class 530, subclass 300+.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions 123-126 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 1-122 and 127-128 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 123/125 and 9-16, 17-19, 23, 25-38, 74-80, 87-92, 99, 101, 103, 105-107, 111-116 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed and the antibody product as claimed can be used in a materially different process such as a method of producing antibody to polypeptide and a method of producing anti-idiotypic antibody, respectively.

The inventions of Groups 124/126 and 1-8, 20-22, 24, 49-73, 81-86, 93-98, 100, 103, 104, 108-110, 117-122 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as

claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product and the probe product as claimed can be used in a materially different process such as hybridization methods to discover species homologues.

The inventions of Groups 124/126 and 9-16, 17-19, 23, 25-38, 74-80, 87-92, 99, 101, 103, 105-107, 111-116 are not at all related because the polynucleotide products of 124/126 are not used in the methods of 9-16, 17-19, 23, 25-38, 74-80, 87-92, 99, 101, 103, 105-107, 111-116.

The inventions of Groups 123/124 and 1-8, 20-22, 24, 49-73, 81-86, 93-98, 100, 103, 104, 108-110, 117-122 are not at all related because the polypeptide/antibody products of Groups 123-125 are not used in the methods of 1-8, 20-22, 24, 49-73, 81-86, 93-98, 100, 103, 104, 108-110, 117-122.

The inventions of Groups 127 and 128 do not appear to be related to Groups 123-126 because it does not appear that the products of Groups 123-126 are used in the methods of Groups 127-128.

Inventions 17-22 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for

screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Inventions 25-72 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Inventions 75-86 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Inventions 87-98 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the

patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Inventions 105-110 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Inventions 11-122 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and

solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
August 25, 2004